(i) connectors extend from said external thermal element along said multi-lumen main body portion for connection to a thermal element housing at the proximal end of said multi-lumen main body portion;

(j) at least one lumen of said multi-lumen main body portion comprises an injectate lumen;

(k) said external thermal element and said temperature measurement apparatus are operative with an external apparatus for providing a measurement of continuous cardiac output of a patient;

(l) said fiber optic apparatus is cooperative with said external apparatus for providing a measurement of mixed venous oxygen saturation of blood of the patient; and

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(m) said injectate lumen has surfaces defining a port, said port being positioned along said multi-lumen main body portion such that, when the distal tip of said main body portion is in a pulmonary artery of a patient, said port is in the right atrium or the superior vena cava of the heart of the patient.--

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REMARKS

I. **Introduction**

Favorable reconsideration of this application is respectfully requested under 37 CFR 1.129(a).

Claims 45-64 are now present. Claims 45, 46, 57, 58, 61, and 64 are the independent claims.

The office action: (1) indicates that the interference requested by the applicant has not been set up; (2) objects to the drawings under 37 CFR 1.83(a); (3) objects to the specification under 37 CFR 1.75(d)(1); (4) rejects claims 62 and 63 and objects to the specification for the reasons applicable to claims 62 and 63 under the first paragraph of 35 USC 112; (5) rejects claims 45 and 53-60 and objects to the specification for the same reasons applicable to claim 45 and 53-60 under the first paragraph of 35 USC 112; (6) rejects claims 45, 53, 54, 56-58, and 61-63 based upon United States patent 4,718,423 to Willis et al. (hereinafter referred to as "the Willis et al. patent") in view of United States patent 4,217,910 to Khalil (hereinafter referred to as "the Khalil '910 patent") under 35 USC 103; (7) rejects claim 55 based upon the combination of the Willis et al. patent and the Khalil '910 patent further modified by the teachings of United States patent 4,814,586 to Grise (hereinafter referred to as "the Grise patent") under 35 USC 103; (8) indicates that claims 46-52 are allowable; and (9) indicates that claims 59 and 60 contain allowable subject matter.

II. **The Request for an Interference**

The office action states:

> The examiner acknowledges applicant's request under 37 C.F.R. §1.607 to provoke an interference with U.S. patent number 5,435,308 to Gallup et al. However, all of the independent claims of the patent recite a pressure port located between the heating element and the distal end of the catheter. Applicant cannot make this claim. Applicant has now amended the claim to

> recite a port. However, no location of the port has been recited. The examiner notes that during prosecution of the Gallup et al patent, claims 1-6 were rejected over Moran (4,776,340) in view of Kalil (4,217,910), while claim 7, which was the location of the pressure port between the distal end of the catheter and the heating element, was indicated to defined [sic; define] over the art. The examiner further notes that Moran, the base reference, had a port. Therefore, the location of the port was the patentable feature. Accordingly, it is the examiner's conclusion that the claims of the Gallup et al patent, which define the location of the port, are patentably distinct, as defined by 37 C.F.R. §1.601, from the present claims. Accordingly, the interference has not been set up by the examiner.[1]

In reply, it is respectfully submitted that the rationale for the denial of the request for interference is illogical for the reasons submitted in applicants' previously submitted request for reconsideration of the denial of the 37 CFR 1.607 request for an interference. Since that request has not yet been acted on, applicants will not burden the record by repeating those arguments here.

III. **The Objection to the Drawings**

The office action states that:

> The drawings are objected to under 37 C.F.R. §183(a). The drawings must show every feature of the invention specified in the claims. Therefore, the fiber optic filaments inside the lumen and the fiber optic coupler associated with the catheter must be shown or the feature canceled from the claim. No new matter should be entered.[2]

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[1]Office action page 2 lines 1-20.

[2]Office action page 2 line 21 to page 3 line 2.

In reply, please find submitted herewith a letter requesting approval of drawings changes and new draft figures 9 and 10. The specification has been amended to provide references to new figures 9 and 10. No new matter has been added.

IV. **The Objection to the Specification Under 37 CFR 1.75(d)(1)**

The office action states that:

> The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 C.F.R. §1.75(d)(1) and M.P.E.P. §608.01(1). Correction of the following is required: Applicant does not have corresponding terminology in the specification to the fiber optic coupler and the filaments, as required by the rule.[3]

In reply, the specification has been amended to provide proper antecedent basis for the claimed subject matter. No new matter has been added.

V. **The Rejections of Claims 62 an 63 and the Corresponding Objection to the Specification**

The office action states that:

> The specification is objected to under 35 U.S.C. §112, first paragraph, as the specification, as originally filed, fails to provide support for the invention, as is now claimed. Claims 62 and 63 recite that the lumen dedicated to measuring distal catheter pressure includes surface defining a port and that the port is for measuring distal catheter pressure. Applicant points to page 16, lines 35-37 and page 24, line 32, as providing support for these features. However, upon review of this sections [sic; section] of the disclosure, no mention of a port in connection to

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[3]Office action page 3 lines 3-8.

> the pressure measuring lumen for measuring distal catheter pressure is made. Accordingly, claims 62 and 63 introduce new matter. Clarification is required.[4]

In reply, it is respectfully submitted that page 16 lines 35-37 and page 24 line 32 would have meant to one of ordinary skill in this art as of the January 29, 1991 priority date for this application (1) that the catheter disclosed in this application had surfaces defining a port and (2) that that port was for measuring distal catheter pressure. For example, United States patent 5,097,840 to Wallace et al. (hereinafter referred to as "the Wallace et al. '840 patent"[5]) discloses (1) that a PA lumen means a lumen that opens directly into the pulmonary artery when the CV lumen is positioned within the right atrium of the heart and (2) that the pressure multiplexing valve 44 provides the proper interconnections between the CV and PA lumens 14, 16 for the purpose of multiplexing a pressure sensor between the two lumens <u>in order to measure pressures at the openings of the CV lumen and the PA lumen</u> with the single pressure sensor.[6] United States patent 4,949,723 to Wallace et al. (hereinafter referred

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[4]Office action page 3 line 18 to page 4 lien 2.

[5]A copy of a Lexus printout of relevant portions of the Wallace et al. '840 patent is attachment 1 to this amendment; a complete copy of the Wallace et al. '840 patent is attachment 2 to this amendment.

[6]The Wallace et al. '840 patent column 1 lines 53-63; column 2 lines 61-66; column 3 lines 49-54; column 9 lines 3-7; column 5 lines 8-15 and 32-34; and column 9 lines 3-7 and 15-19.

to as "the Wallace et al. '723 patent"[7]) also provides the teachings in the Wallace et al. '840 patent. Thus, the disclosure of the PA distal lumen hub 108 of the PA lumen at page 16 line 37 in the specification meant to one ordinary skill in this art as of January 29, 1991 a lumen having a port for measuring the pressure of the pulmonary artery.

Moreover, the specification discloses both a proximal fluid infusion port and a distal fluid infusion port.[8] The specification discloses that the proximal port is located in the right atrium or superior vena cava when the distal tip of the catheter is in the pulmonary artery. The specification also discloses that the distal port is located in the right ventrical when the distal tip of the catheter is located in the pulmonary artery. The disclosure of the distal port would have meant to one of ordinary skill in this art that that port could be used for, among other things, measuring distal catheter pressure. This is so because it is well known in the art that the port near the end of the catheter can be used for both pressure measurement and fluid infusion.[9] Therefore, the disclosure in the specification of the distal fluid infusion port supports the port defined in claims 62 and 63.

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[7]A copy of the Wallace et al. '723 patent is attachment 3 to this amendment.

[8]Specification page 22 lines 3-12.

[9]The Wallace et al. '840 patent column 5 lines 28-49.

For the foregoing reasons, it is submitted that the subject matter defined by claims 62 and 63 is disclosed and enabled by the specification.

VI. The Rejections of Claims 45 and 53-60 and the Corresponding Objection to the Specification

The office action states that:

> The specification is objected to under 35 U.S.C. §112, first paragraph, as failing to provide an enabling description of the claimed invention. Claims 45, and 57-60 recite a port to enable injection of a fluid into the bloodstream. While there is basis for the injectate port, it is unclear from the specification what the purpose of injecting fluid is, as the principle of operation of the device is to add heat, not a cold bolus, for measuring cardiac output. Applicant should clarify the purpose of the fluid injection. Clarification is required.
>
> Claims 45, 53-63 [sic] are rejected under 35 U.S.C. §112, first paragraph, for the reasons set forth in the objection to the specification.[10]

In reply, it is respectfully submitted that the objection and corresponding rejection of claims 45 and 53-60 is without merit for several reasons.

First, this application discloses and claims a catheter, not a method of use. Thus, the fact that the specification discloses ports[11] provides support for the subject matter defined by apparatus claims 45 and 53-60.

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[10]Office action page 4 lines 3-15.

[11]See, e.g., the specification page 22 lines 3-12.

Second, it is notoriously old and well known in the art to include fluid infusion ports (1) in catheters and (2), in particular, in catheters that are intended to monitor or operate upon the heart. Thus, it would have been immediately apparent to one of ordinary skill in the art that the ports defined by the subject matter of claims 45 and 53-60 have utility, and it would have been immediately obvious to one of ordinary skill in the art how to use the ports of the subject matter defined by claims 45 and 53-60 for several different purposes. Therefore, one of ordinary skill in this art would have known how to use those ports.[12] The following United States patents evidence these facts: United States patent 3,792,703 to Moorhead (hereinafter referred to as "the Moorhead patent"[13]); United States patent 4,802,479 to Haber et al. (hereinafter referred to as "the Haber et al. patent"[14]); United States patent 4,800,886 to Nestor (hereinafter referred to as "the Nestor patent"[15]); United States patent 4,723,556 to Sussman (hereinafter referred to as "the

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[12]Carter-Wallace, Inc. v. Davis-Edwards Pharmacal Corp., 341 F.Supp. 1303, 1324, 173 USPQ 65, 104 (E.D.N.Y. 1972); aff'd. 474 F.2d 529, 176 USPQ (2nd Cir. 1972).

[13]A copy of the Moorhead patent is attachment 4 to the amendment. A copy of a Lexis printout of portions of the Moorhead patent is attachment 5 to the amendment.

[14]A copy of the Haber et al. patent is attachment 6 to the amendment. A copy of a Lexis printout of portions of the Haber patent is attachment 7 to the amendment.

[15]A copy of the Nestor patent is attachment 8 to the amendment. A copy of a Lexis printout of portions of the Nestor patent is attachment 9 to the amendment.

Sussman patent"[16]; and United States patent 4,559,046 to Groshong et al. (hereinafter referred to as "the Groshong et al. patent"[17]). Moreover, the Wallace et al. '840 patent and the Wallace et al. '723 patent also evidence these assertions.

For the foregoing reasons, it is respectfully submitted that the subject matter defined by claims 45 and 53-60 is disclosed and enabled by the specification.

VII. **The Rejections of Claims 45, 53, 54, 56-68, and 61-63 Based Upon the Willis et al. Patent in view of the Khalil '910 Patent**

The office action states that:

> Claims 45, 53, 54, 56-58, and 61-63 are rejected under 35 U.S.C. §103 as being unpatentable over Willis et al in view of Khalil '910. Willis et al shows all of the features of the claims except that it measured cardiac output using a cold bolus injection. Khalil teaches that cold bolus injections and using external heaters heat the blood are equivalent methods of measuring cardiac output (see background section). Accordingly, it would have been obvious to modify Willis et al to use a heating coil, rather than a cold bolus injection, as it is merely the substitution of one known equivalent measurement technique for another. Claim 54 is rejected in that the exact distance between the end of the catheter and the heater varies with catheter size and would have been obvious to o ne skilled int he [sic; in the] art. Claims 56-58 and 61-63 are rejected in that the combination shows all of the features of the claims.[18]

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[16]A copy of the Sussman patent is attachment 10 to the amendment. A copy of a Lexis printout of portions of the Sussman patent is attachment 11 to the amendment.

[17]A copy of the Groshong et al. patent is attachment 12 to the amendment. A copy of a Lexis printout of portions of the Groshong et al. patent is attachment 13 to the amendment.

[18]Office action page 5 lines 6-20.

In reply, independent claims 45, 57, 58, and 61 have been amended to define over the combinational structure provided by the modification of the catheter disclosed in the Willis et al. patent, including the external heaters to heat the blood of the catheter disclosed in the Khalil '910 patent.

Independent claim 45 has been amended to define a necked-down portion on which the external thermal element is mounted.

Independent claim 57 has been amended to recite the second port disclosed in the first full paragraph on page 22 of the specification.

Independent claim 58 has been amended to recite the position of the port when the distal tip of the catheter is in the pulmonary artery, as disclosed in the first full paragraph on page 22 of the specification.

Independent claim 61 has been amended to recite that "said wiring and said fiber optic filaments are disposed in different lumens."

The subject matter defined by claim 61 would not have been obvious in view of the combination of the Willis et al. patent in view of the Khalil '910 patent because that combination includes the location of the fiber optical filaments and the wiring in a single lumen.[19] Thus, the proposed combinational structure is not the subject matter defined by independent claim 61.

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[19]The Willis et al. patent column 3 line 59 to column 4 line 21; the lumen T/F shown in figure 2; and the description of the leads T and the fibers F shown in the lumen T/F in figure 2 at column 6 lines 65-67.

Dependent claims 53-56 depend from independent claim 45. Dependent claims 62 and 63 depend from independent claim 61. Therefore, for the reasons presented with respect to independent claims 45 and 61, the proposed combinational structure is not the subject matter defined by any one of these dependent claims.

Moreover, new independent claim 64 is modeled after independent claim 58 and recites an alternative position of the port when the distal tip of the catheter is in the pulmonary artery, as disclosed in the first full paragraph on page 22 of the specification.

VIII. The Rejection of claim 55 Based Upon the Willis et al. Patent in view of the Khalil '910 Patent and the Grise Patent

The office action states that:

> Claim 55 is rejected under 35 U.S.C. §103 as being unpatentable over Willis et al in view of Khalil as applied to claims 45, 53, 54, 56-58, and 61-63 above, and further in view of Grise. Grise teaches that a substrate based heater is an improvement over a single wire of Khalil, in that the cost is much less and the heaters are more flexible in use. Accordingly, it would have been obvious to modify the above combination to use the substrate based heater of Grise, for the reasons given above.[20]

In reply, it is respectfully submitted that claim 55 is allowable at least for the reasons that apply to claim 45, from which it directly depends.

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[20]Office action page 5 line 21 to page 6 line 3.

Moreover, the Grise patent does not disclose or suggest (1) any element corresponding in structure to the recited external thermal element, (2) a heating filament printed on two opposing sides of a substrate, or (3) that the substrate is suitable for incorporation into an external thermal element of a multilumen multipurpose cardiac catheter. These additional elements are defined by claim 55. For these additional reasons, it would not have been obvious to modify the combinational structure in view of the teachings of the Grise patent to be subject matter defined by claim 55.

IX. **Conclusion**

It is submitted that all of the claims of this application are now allowable. Therefore, the examiner is requested to fill out the initial interference memorandum and forward this application to the Board of Patent Appeals and Interferences for declaration of the interference.

X. **Addendum**

The undersigned is conveniently located within walking distance of the examiner's office. The undersigned hereby requests a personal interview with the examiner for the purpose

of overcoming any outstanding issues in order to expedite the declaration of the interference.

Respectfully submitted,

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